

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Dorchak on 7/1/09.

The application has been amended as follows:

Please **cancel Claim 18**.

Please **replace claim 17** with the following:

Claim 17 (Currently amended): Microparticles stable and storable at room temperature of insulin,

- showing a d₉₀ volume diameter lower than 9 μm ,
- 80% of them exhibiting an aerodynamic diameter lower than 5 μm ,
- having corrugated or raisin-like surface and
- having a moisture content in the range of 2 to 8%, said microparticles having a tapped density lower than 0.2 g/cm³ and being obtained by spray drying an aqueous solution of insulin having an acid pH under the isoelectric point (5.4) of insulin and a concentration of insulin in amounts of from 5 to 100 mg/ml, said aqueous solution being prepared in an unbuffered aqueous solution of acetic acid.

Please **replace claim 19** with the following:

Claim 19 (Currently amended): Microparticles according to claim 17, wherein insulin is in association with excipients selected from the group consisting of saccharides, polysaccharides, amino acids, phospholipids and polyalcohol.

Mr. Dorchak was again contacted on 7/13/09 to submit an amendment to specification to incorporate "Brief descriptions to drawings" to appear on page 7 of the specification to correct a deficiency noted during processing.

The 'Information disclosure statements' filed on 1/3/07 and 1/19/07 have been annotated to correct a missing date for one of the references listed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Andrew D Kosar/
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